REMARKS / ARGUMENTS

Claims 5-13 were rejected under 35 USC 112, first paragraph, for failing to meet the enablement requirement. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

MPEP Section 2107.02, provides the following guidance for analyzing a therapeutic utility.

> Before a drug can enter human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those especially skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility. (Emphasis in original.)

This analysis, which takes into consideration, a drugs effectiveness, can also be applied in the context of enablement.

As further support of the enablement of the present invention, attached hereto as Exhibit 1 is a printout from the website www.clinicaltrails.gov, a service of the U.S. National Institutes of Health, showing the claimed combination therapy, PTK787, aka vatalanib, was tested in two clinical trials with temozolomide. Attached as Exhibit 2 is a webpage from the National Cancer Institute Confirming that PTK787 is also called vatalanib. Because the presently claimed invention has been tested in therapeutic trails, applicants urge that the present specification, which describes a treatment PTK787 and temolozolomide in Example 1, provides enablement. Accordingly, the rejection for lack of enablement should be withdrawn.

Claims 5-8 and 10-13 were rejected under 35 USC 112, second paragraph. Applicant requests reconsideration and withdrawal of this rejection for the reasons that follow.

The claims have been amended to specify that the tumor related disease is glioblastoma, thereby rendering this rejection moot.

Claims 1-13 were rejected under 35 USC 102(a) as anticipated by Wood et al. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

Although Wood et al includes alkylating agents in a list of potential combination partners for the disclosed VEGFR tyrosine kinase inhibitors, the Examiner does not point out any disclosure of an actual combination of PTK787 and temozomide. Therefore, Wood et al does not anticipate the presently claimed invention. Applicant further points out that Wood et al does not even suggest many of the limitations found in the present dependent claims and therefore clearly does not anticipate those dependent claims.

Claims 1-13 were rejected under 35 USC 103(a) over Bold in view of Reidenberg. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

Bold is relied on as disclosing the present compounds of formula I and PTK787. Reidenberg is relied on as disclosing temozolomide as a chemotherapeutic agent.

Bold describes a genus of pyridazine compounds that can be use to treat "a number of diseases associated with deregulated angiogenesis, especially retinopathies, psoriasis, hemangioblastoma, hemangioma, and especially neoplastic diseases (solid tumors), such as especially breast cancer, cancer of the colon, lung cancer (especially small-cell lung cancer), or cancer of the prostate." (Col. 10, lines 53-68). Reidenberg describes that temozolomide can be used to cancers including "melanoma; high grade glioma, glioblastoma and other brain cancers; lung cancer; breast cancer; testicular cancer; gastro intestinal cancers including colon, rectal, pancreatic, and gastric cancers, hepatocellular carcinoma; head and neck cancers; prostate cancer, renal cell carcinoma; adenocarcinoma; sarcomas; lymphomas; leukemias; and mycosis fungoides."

Due to numerous compounds described by Bold and the various types of cancers described by Bold and Reidenberg, applicants contend that it would not be obvious to arrive at the present invention. This is not a case of a choosing from a small number of options to arrive at a predictable outcome. Rather, one of ordinary skill in the art would have to pick from a large array of potential compounds, and chose a specific type of cancer for treatment, in an unpredictable field. Such a selection would not have been obvious, and without hindsight knowledge of the present invention, would have been improbable.

Accordingly, the present invention is not obvious and under 35 USC 103, applicant requests withdrawal of this rejection.

Respectfully submitted,

Novartis Pharmaceuticals Corp.
Patents Pharma
One Health Plaza, Building 101
East Hanover, NJ 07936-1080
(862) 778-4872

Matthew E. Mulkeen
Attorney for Applicant
Reg. No. 44,250

Date: May 25, 2009

Found 2 studies with search of: vatalanib temozolomide

Hide studies that are not seeking new volunteers.

Display Options

Rank	Status	Study
1	Recruiting	**PTK787/ZK 222584 in Combination With Temozolomide and Radiation in Patients With Glioblastoma Taking Enzyme-Inducing Anti-Epileptic Drugs** Condition: Glioblastoma Interventions: Drug: PTK787/ZK 222584; Drug: Temozolomide; Procedure: Radiation Therapy
2	Active, not recruiting	**Temozolomide and Radiation Therapy With or Without Vatalanib in Treating Patients With Newly Diagnosed Glioblastoma Multiforme** Condition: Brain and Central Nervous System Tumors Interventions: Drug: temozolomide; Drug: vatalanib; Procedure: adjuvant therapy; Radiation: radiation therapy

Save this search by bookmarking this page.
When you use your bookmark, the search will be performed again on the most recent collection of studies.

RSS Feed for studies found by your search that were received in the last 14 days

Download Options

EXHIBIT 1

National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov

Send to Printer

NCI Drug Dictionary

vatalanib
An orally bioavailable anilinophthalazine with potential antineoplastic activity. Vatalanib binds to and inhibits kinase domain of vascular endothelial growth factor receptors 1 and 2; both receptor tyrosine kinases are invol angiogenesis. This agent also binds to and inhibits related receptor tyrosine kinases, including platelet-derived (PDGF) receptor, c-Kit, and c-Fms. Check for active clinical trials or closed clinical trials using this agent. (N

Synonyms:
CGP79787D
PTK787/ZK 222584

Code names:
CGP-79787
PTK787
ZK 222584

Chemical structure names:
* 1-[4-Chloroanilino]-4-[4-pyridylmethyl]phthalazine Succinate
* 1-Phthalazinamine, N-(4-chlorophenyl)-4-(4-pyridinylmethyl)-, butanedioate (1:1)

Previous: Vantin, Vaqta, varenicline, vascular disrupting agent CYT997, Vasomax

Next: VCL-CB01 vaccine, Vectibix, vector-peptide conjugated paclitaxel, Vectrin, VEGFR-2 inhibitor peptide CT-322

EXHIBIT 2